



Standard Operating Procedure Document Control

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ECN #:
Effective:

SOP 4-002

Revision: 1

1.0 Purpose

- 1.1 The purpose of this procedure is to provide a system for editing, issuing, and controlling documents deemed as necessary by GMP requirements and company management.

2.0 Scope

- 2.1 Company documents are maintained under document control as described by this procedure.
- 2.2 This procedure will also apply to business procedures and other documents not required by GMP's but deemed necessary by the company management. All documents that are required by GMP and management are to be maintained under formal document control.

3.0 Applicable Documents

- 3.1 SOP 4-001 Engineering Change Notice
- 3.2 SOP 4-003 Records Retention Procedure
- 3.3 SOP 4-006 Specification Format Procedure
- 3.4 QMSM Quality Management System Manual
- 3.5 Attachment A: Engineering Change Notice Checklist
- 3.6 Attachment B: Notification and Receipt Sheet
- 3.7 Attachment C: Document Distribution Sheet

4.0 Definitions

- 4.1 Approval Cycle: That period in the life of an ECN from the time that it is placed into the review process to the time that the last required approval signature has been obtained.
- 4.2 Device Master Record (DMR): A compilation of records containing, but not limited to, the design, formulation, specifications, complete manufacturing procedures, quality assurance requirements, packaging requirements and labeling of a finished device.
- 4.3 Document Control System: The Document Control System deployed at the company is a paper-based system, which utilizes some on-line tools found on the company's intranet. Examples of these tools are email and shared folders with varied security features.
- 4.4 Document: Any manual or electronic record of a text or graphics image that represents a drawing, parts list, Bill of Material, purchasing specification, process specification, assembly procedure, test or inspection procedure, business procedure, etc., relating to products processed or administrated under the control of the company's Document Control Department.

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